



Winter 2003

# CLIA BITS



North Dakota Department of Health  
Division of Health Facilities

## Most Commonly Cited Deficiencies

The following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Jan. 1, 2002, through Dec. 31, 2002.

- D7047 – Comparison of Test Results. This requirement states that if a laboratory performs tests that are not included under Subpart I, Proficiency Testing Program, the laboratory must have a system for verifying the accuracy and reliability of its test results twice a year.
- D3056 – Test Report. The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result and, if applicable, the units of measurement.
- D4006 – Moderate Complexity Testing. This requirement states that a laboratory must perform and document control procedures using at least two levels of control materials each day of testing.
- D3037 – Test Records. This deficiency is cited when a laboratory's record system fails to include the patient identification number, accession number or other unique identification number.
- D2015 – Testing of Proficiency Samples. This requirement states that a

laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results, for a minimum of two years from the date of the proficiency testing event.

- D6126 – Technical Supervisor Responsibilities. The procedures for evaluation of the competency of the staff must include assessment of problem-solving skills.

Take a close look at your laboratory and identify if it is deficient in these areas, and, if so, take the corrective actions necessary to fix these areas prior to your next survey. If you have any questions about the deficiencies or the requirements, please contact the North Dakota Department of Health, Division of Health Facilities, at 701.328.2352.

The North Dakota Department of Health CLIA program website has a new address:  
[www.health.state.nd.us/hf/CLIA/default.htm](http://www.health.state.nd.us/hf/CLIA/default.htm).

## HIPAA News

HIPAA is an acronym for the Health Insurance Portability and Accountability Act, signed into law in 1996. The intent of HIPAA is to improve the portability and continuity of health insurance coverage; to combat waste, fraud and abuse in health care insurance; and to simplify the administration of health services. Title II of HIPAA includes Administrative Simplification, which requires improved efficiency in health care delivery by standardizing electronic data interchange and requires the privacy and security of health data. All health plans, health care clearinghouses and health care providers who transmit health information in an electronic format are considered covered entities and must comply with HIPAA.

More information is available at [www.discovernd.com/hipaa](http://www.discovernd.com/hipaa).

Our office frequently is asked about a facility's responsibilities regarding HIPAA when it comes to survey activities.

Section 164.512, uses and disclosures for which an authorization or opportunity to agree or object is not required, states:

(d) *Standard: Uses and disclosures for health oversight activities.*

(1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

- (i) The health care system;
- (ii) Government benefit programs for which health information is relevant to beneficiary eligibility;
- (iii) Entities subject to government regulatory programs for which health

information is necessary for determining compliance with program standards; or  
(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

## Approval of New Rapid HIV Test

On Nov. 7, 2002, the Food and Drug Administration (FDA) announced approval of the OraQuick Rapid HIV-1 Antibody Test for use as a point-of-care test to aid in the diagnosis of human immunodeficiency virus type 1 (HIV-1) infection. OraSure Technologies Inc. manufactures the OraQuick Rapid HIV-1 Antibody test. Results are provided in about 20 minutes from a fingerstick whole-blood specimen. The test has been categorized as a moderate complexity test under CLIA. More information can be found in the Nov. 22, 2002, edition of the MMWR online at [www.cdc.gov/mmwr/PDF.wk/mm5146.PDF](http://www.cdc.gov/mmwr/PDF.wk/mm5146.PDF).

Sometime in the future, CLIA Bits will be sent electronically. To assist us with this endeavor, please send your facility or laboratory email address to [bweidner@state.nd.us](mailto:bweidner@state.nd.us) by Jan. 31, 2003.



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